UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/092,138 | 03/06/2002 | Taka-Aki Sato | 65823/JPW/PT | 8978 |

7590 12/03/2002

John P. White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

| EXAMINER | |
|---|---|
| WESSENDORF, TERESA D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | 7 |

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 10/092,138 | Applicant(s) SATO, TAKA-AKI | |
|---|---|---|---|
| | Examiner T. D. Wessendorf | Art Unit 1639 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *11 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Specification*

The abstract of the disclosure is objected to because of the used of the term often used in patent claims, e.g., "comprising". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because of the following informalities:

1. The status of applications S.N. 08/681,219 or 09/230,111 recited at page 17, lines 7-10 have not been provided.

2. There is no Seq. ID. No. for sequence GLGF recited at page2, line 27 of the instant specification. Applicants are requested to check for other Sequences in the specification that do not have ID. Nos.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112, first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described

in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide a written description for the claimed method of preparing a protein array with the protein elements either alone or in combination with the other elements such as oligonucleotide, DNA, mRNA, sugar. There is no description as to whether the array comprises each of the different elements or form a part of the protein molecule. The description in the specification repeats only what is in the claims and simply states that the array has said other components. It is not readily apparent from the Examples provided therein whether a protein array has been prepared. All of the Examples relate to screening a random library and the inhibitory effect of a tripeptide between the Fas-Fap interactions. (It is of interest to note that all the Examples in the instant specification are the same as that in U.S. 2002/0058607).

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the intervening steps between (a) and (b) steps. It is not clear as to the conditions that result in a protein-protein interaction after deposition of the first protein and before application of the second protein, especially in the absence of positive recitation in the specification as to the steps. It is not clear whether the Alternative tripeptide is applied individually or a library containing the alternative groups. The language "selected from the group comprising" is an improper Markush language. It is suggested that comprising be changed to "consisting". It is further suggested that the twenty amino acid residues be recited.

2. Claim 3 is indefinite and broadens the base claim 1 with the recitation that the 'array is used to screen one or more

drug targets. The base claim recites only a method of preparing and not a screening method. Also, there is no recitation in the base claim of a physiological condition.

3. The language in claim 13 of "at least one a sugar" is grammatically incorrect.

4. Claims 10-23 and 17-20 are confusing and unclear as to whether each of these compounds form a part of the protein molecule or are separate, discrete components of the protein array, especially in the absence of positive teaching or showing in the specification as to how such array are prepared with these different compounds.

5. The term 'corresponding' PDZ domain, within the claimed context, is indefinite as in what manner or what constitutes a corresponding PDZ domain. [Claim 14].

6. Claim 16 is indefinite as there is inconsistency between the preamble and the body of the claim. The preamble recites for a protein array while the body recites for making a polypeptide.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

> the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle (Cell) in view of any one of applicant's disclosure of known prior art or Schneider-Mergener (Comparative and Functional Genomics) or Harris et al (Jrnl. of Cell Science).

Doyle discloses, page 1067 a modular PDZ domain that binds to the peptide motif T/S-X-Val at the C-terminus of protein K Channels and NMDA receptor ion channels. Doyle further discloses at page 1072 that Val can be varied with Ile. Doyle does not disclose a method of preparing an array for the PDZ domain with its receptor. However, applicant discloses at page 3, lines 23-34 that a "recent trend in biology, biotechnology and medicine is the use of arrays of immobilized biological compounds in studies of immunoassays and enzymatic reactions (see Mendoza….) For example, mass sensing, multianalyte microarray immunoassays have been performed (Rowe et al…) The use of arrays allows for large scale and high-throughput studies of multiple samples in parallel. Integration of microarray technology into the experimental methodology also may increase efficiency in many instances, such as through reducing the volume of samples and reagents required.." Harris et al disclose

an array of target proteins to which PDZ containing proteins bind to. See the abstract. Schneider discloses that an array is a versatile toolbox for a variety of application in proteomics. See the abstract. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare or to format the PDZ domains of Doyle into an array since forming a compound into an array will provide a high- throughput screening for a desired receptor or ligand, as taught by applicant's disclosure and Schneider. This is evident from the teachings of Harris, which discloses an array of target receptors for the PDZ domain.

Claim 14 is obvious over the teachings of Doyle at page 1067 disclosing the different corresponding PDZ domain.

Claim 16 is obvious over the teachings of Doyle as to the proteins or polypeptides of PDZ domain at page 1067, col. 2.

No claim is allowed.

~~CFR 1.17(1)~~.

**REASSIGNMENT OF LOCATION**

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw

December 1, 2002

investigated expression of GIPC2 mRNA in human gastric, pancreatic, and breast cancer cell lines. GIPC2 mRNA was relatively highly expressed in OKAJIMA, TMK1, MKN45, and KATO-III cells derived from diffuse type of gastric cancer, but was almost undetectable in MKN7, MKN28, and MKN74 cells derived from intestinal type of gastric cancer as well as in other cell lines derived from pancreatic and breast cancer. Tumor necrosis factor .alpha. and interferon .gamma., which are elevated in gastric mucosa with Helicobacter pylori infection, did not affect the expression level of GIPC2 mRNA in MKN45 cells. Up-regulation of GIPC2 mRNA was detected in 7 out of 10 cases of primary gastric cancer by using cDNA-PCR, and in 4 out of another 8 cases of primary gastric cancer by using expression **array** filter hybridization. GIPC2 might play important roles in human gastric cancer through modulation of growth factor signaling or cell adhesion.

L2 ANSWER 2 OF 7 CA COPYRIGHT 2002 ACS
AU Mandal, Pravat K.
SO Monatshefte fuer Chemie (2002), 133(2), 205-217
CODEN: MOCMB7; ISSN: 0026-9247
PY 2002
AB PDZ domains are found in a wide **array** of proteins possessing various biol. functions like clustering membrane proteins, organizing signal transduction complexes, and maintaining cell polarity. This report presents a complete chem. shift assignment of the **PDZ domain** of neuronal nitric oxide synthase. The secondary structure based on C.alpha. and C.beta. chem. shifts is presented.

L2 ANSWER 3 OF 7 CA COPYRIGHT 2002 ACS
AU Schneider-Mergener, Jens
SO Comparative and Functional Genomics (2001), 2(5), 307-309
CODEN: CFGOAT; ISSN: 1531-6912
PY 2001
AB The SPOT technol. for highly parallel synthesis of peptides on flat surfaces in **array** type format has evolved into a versatile toolbox for a variety of applications in proteomics such as mapping protein-protein interactions and profiling the substrate specificity of enzymes such as kinases and proteases. Originally developed for the synthesis of short overlapping peptide sequences for mapping antibody epitopes this technol. has recently been extended to the synthesis of functional protein domains. This opens up a variety of future applications such as target identification and protein expression profiling.

L2 ANSWER 4 OF 7 CA COPYRIGHT 2002 ACS
AU Harris, Baruch Z.; Lim, Wendell A.
SO Journal of Cell Science (2001), 114(18), 3219-3231
CODEN: JNCSAI; ISSN: 0021-9533
PY 2001
AB A review. PDZ domains are protein-protein recognition modules that play a central role in organizing diverse cell signaling assemblies. These domains specifically recognize short C-terminal peptide motifs, but can also recognize internal sequences that structurally mimic a terminus. PDZ domains can therefore be used in combination to bind an **array** of target proteins or to oligomerize into branched networks. Several **PDZ-domain**-contg. proteins play an important role in the transport, localization and assembly of supramol. signaling complexes. Examples of such PDZ-mediated assemblies exist in Drosophila photoreceptor cells and at mammalian synapses. The predominance of PDZ domains in metazoans indicates that this highly specialized scaffolding module probably evolved in response to the increased signaling needs of multicellular organisms.

L2 ANSWER 5 OF 7 CA COPYRIGHT 2002 ACS
AU Yokota, Toshifumi; Miyagoe, Yuko; Hosaka, Yukio; Tsukita, Kayoko; Kameya, Shuhei; Shibuya, Seiji; Matsuda, Ryoichi; Wakayama, Yoshihiro; Takeda,